

## **REMARKS**

Claims 1-15 are canceled. Claims 16-26 are added. Support for the new claims is found in the specification as filed, see, e.g., paragraph [0071] of Pub. No. US 2004/0137581 A1.

### **Claim Objections**

Claims 1-5 were objected to as reciting non-elected subject matter. Claims 1-5 have been canceled. New claims 16-26 all recite elected subject matter. Applicants respectfully request the objection to the claims be withdrawn.

### **Claim Rejection Under 35 U.S.C. § 101**

Claims 1-5 were rejected as being directed to non-statutory subject matter, specifically that variant IFN proteins within the scope of the claims may already be present in nature. Claims 1-5 have been canceled. In order to further prosecution on the merits, new claims 16-26 recite the term "isolated" as suggested by the Examiner. Applicants respectfully request the rejection under 35 U.S.C. § 101 be withdrawn.

### **Claim Rejection Under 35 U.S.C. § 112, First Paragraph – Enablement**

1. Claims 1-5 were rejected under 35 U.S.C. § 112, first paragraph and not being enabled for all interferon types. Claims 1-5 have been canceled. The Office Action states, "the specification, while being enabled for the variant type I IFN- $\beta$  polypeptides comprising a substitution at position 8 as described in the specification...." New claims 16-26 recite IFN- $\beta$  comprising a substitution at position 8, which is enabled according to the Office Action. Applicants respectfully request this rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

2. Claims 1-5 were rejected under 35 U.S.C. § 112, first paragraph and not being enabled for increased immunogenicity. Claims 1-5 have been canceled, rendering this rejection moot. New claims 16-26 do not recite increased immunogenicity. Applicants respectfully request this rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

### **Claim Rejection Under 35 U.S.C. § 112, First Paragraph – Written Description**

Claims 1-5 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 1-5 are canceled, rendering this rejection moot. New claims 16-26 are described in the specification. See, for example, paragraph [0071] of Pub. No. US 2004/0137581 A1, Example 5 (paragraphs [0175]-[0181]), and SEQ ID Nos. 20-26. Applicants respectfully request this rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

**Claim Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-5 were rejected under 35 U.S.C. § 112, first paragraph as being indefinite. Specifically, claims 1-5 did not recite any wild-type IFN- $\beta$  polypeptide sequence upon which the variant IFN- $\beta$  polypeptide is derived. Claims 1-5 are canceled, rendering this rejection moot. New claims 16-26 specify that the variant IFN- $\beta$  polypeptide is in relation to wild-type human IFN- $\beta$  (SEQ ID NO:15). Applicants respectfully request the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

**Claim Rejection Under 35 U.S.C. § 102**

Claims 1-5 were rejected under 35 U.S.C. § 102, and being anticipated separately by Runkel *et al.* (Biochem. 2000, Vol. 39, p. 2538-2551), Pedersen *et al.* (US 6,531,122), and Bell *et al.* (US 4,738,844).

Runkel

1. The Office Action states that Runkel discloses a variant IFN- $\beta$  comprising alanine substitutions at positions 2, 4, 5, 8, and 11. Claims 1-5 have been canceled, rendering this rejection moot. New claims 16-26 recite the modification F8E. Runkel does not teach or suggest this modification. Applicants respectfully request this rejection under 35 U.S.C. § 102 be withdrawn.

Pedersen

2. The Office Action states that Pedersen teaches replacement of various amino acids, including F8, with other amino acids, including lysine, aspartic acid and glutamic acid. Claims 1-5 have been canceled, rendering the rejection moot.

Applicants respectfully submit that Pedersen does not anticipate new Claims 16-26. Specifically, Pedersen teaches making conjugates of IFN- $\beta$ , and lists 83 possible residues to make an IFN- $\beta$  conjugate using lysine, and 68 possible residues by using either aspartic acid or glutamic acid. Pedersen never specifically recites an IFN- $\beta$  comprising F8E, only lists F8E as one of many possible variants, but not one of the most preferred variants. Considering the vast number of possible variants listed in Pedersen, Applicants respectfully submit that it does not anticipate new Claim 16.

Furthermore, the IFN- $\beta$  variants as taught by Pedersen also comprise a non-polypeptide moiety. The present invention does not comprise a non-polypeptide moiety conjugated at variant amino acid F8E. Applicants respectfully submit that Pedersen does not anticipate independent Claim 16, and claims dependent therefrom.

The Federal Circuit and its predecessor Court have held that broad, generic formulas or descriptions of a large class of compounds, in the absence of the provision of a much more limited subset of specified preferences for *particular* compounds that encompasses the claimed compound, are not sufficient to support an anticipation rejection. Accordingly, Applicants submit Pedersen merely provided a broad generic description representing a large number of compounds which does not unequivocally

disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures.

The Court in *In re Arkley*, 455 F.2d 586, 172 USPQ 524 (CCPA 1972), held that a generic class of compounds having a particular formula did not anticipate the appellant's claimed compound. Applicants respectfully submit that *In re Arkley* applies to the present case. In that decision, the Court stated that:

for the instant rejection under 35 USC 102(e) to have been proper, the... reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.

In addition, with regard to the claimed compound, the *Arkley* Court stated that:

there is nothing in the teachings relied upon by the Patent Office which clearly and unequivocally directs those skilled in the art to make this selection nor any indication that...[the prior art reference]...ever made the selection himself.

Similarly, the Court in *Schering Corp. v. Precision-Cosmet Co.*, 614 F. Supp. 1368, 227 U.S.P.Q. (BNA) 278 (D. Del. 1985), in reviewing a broad prior art disclosure of substituted styrenes with reference to a claimed specific substituted styrene having a particular property, stated that the prior art reference:

does not mention any particular substituted styrene, makes no references to the permeability of specific substituted styrenes, and provides no basis whatever for preferring any sub-group of substitute styrenes over other substituted styrenes.... Given the fact that substituted styrenes comprise a class in excess of one hundred compounds, it seems clear that the elements of the claimed invention...were not adequately described...for purposes of identification; and that one of ordinary skill in the art would have had to engage in extensive experimentation to get from [the prior art disclosure] to the [claimed] invention.

The *Schering* Court also provides the following discussion of anticipation:

The general rule is that a prior genus does not anticipate a later species. I *Chisum, Patents* § 3.02[2] (1985); see *In re Ruschig*, 52 C.C.P.A. 1238, 343 F.2d 965 (C.C.P.A. 1965). If, however, it is possible to derive a class of compounds of lesser scope than the genus disclosed in a prior art reference on the basis of preferences ascertainable from the remainder of the reference, anticipation may be found. *E.g.*, *Application of Schaumann*, 572 F.2d 312, 316 (C.C.P.A. 1978); *In re Petering*, 49 C.C.P.A. 993, 301 F.2d 676, 681 (C.C.P.A. 1962). The anticipating reference must contain within its four corners a sufficient description to enable one to practice the invention without experimentation or inventive skill. *Philips Elec. & Pharmaceutical Indus. Corp. v. Thermal & Elec. Indus., Inc.*, 450 F.2d 1164, 1169 (2d Cir. 1971); *Dewey & Almy Chem. Co. v. Mimex Co.*, 124 F.2d 986, 990 (2d Cir. 1942); I *Chisum, Patents* § 3.04[1][6] (1985). See *CBS v. Sylvania Electric Prod., Inc.*, 415 F.2d 719, 725 (1st Cir. 1969) (test is whether the prior art reference "describes the invention with sufficient clarity and specificity so that one skilled in the art may practice the invention without assistance from the patent claimed to have been anticipated.")

Moreover, the Federal Circuit has recently reaffirmed the longstanding principle that such a broad generic disclosure does not represent the "limited number of specific preferences from a specifically defined group" necessary to clearly name, and thus anticipate, a claimed species. *Eli Lilly & Co.*, 471 F.3d at 1377 (Fed. Cir. 2006).

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Bell

3. Claims 1-4 of the application were rejected under 35 U.S.C. § 102(b) as being anticipated by Bell. Specifically, Bell replaced amino acids 3-28 of IFN- $\beta$  with amino acids 2-26 of IFN- $\alpha$ , resulting in a substitution of histidine at position 8. Claims 1-4 have been cancelled, rendering this objection moot.

New Claim 16 requires F8E, and thus Bell does not anticipate new claim 16 or claims dependent therefrom. Applicants respectfully request the rejection under 35 U.S.C. § 102 be withdrawn.

**Double Patenting**

Claims 1-5 were provisionally rejected on the ground of non-statutory obviousness-type double patenting over co-pending Application No. 10/676,705. The '705 application became abandoned for failure to respond to an office action because the office action was mailed to an old address. Applicants have not revived the '705 application, rendering this rejection moot.

**Conclusion**

Applicants believe the present application is in condition for allowance. Early favorable communication thereof is respectfully requested. Please direct any calls in connection with this application to the undersigned at (415) 442-1000.

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